GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4633
ANSWERED ON:18.12.2002
APPROVAL FOR LEVONORGE
BALIRAM;P.R. KHUTE

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether M/s Cipla had not taken any DCGI approval for launch of Levonorge;

(b) if so, the details thereof; and

(c) the action taken/proposed to be taken by DCGI against the company?

Answer

MINISTER OF HEALTH AND FAMILY WELFARE (SHRI SHATRUGHAN SINHA)

(a) to (c) Levonorgistrel is a contraceptive hormone which was used along with Ethylestradiol as oral contraceptive pill. Levonorgistrel is a very old and established drug which also has Pharmacopoeial monograph in Indian Pharmacopoeia (IP) and other Pharmacopoeias like BP, USP etc. In September, 2001the use of Levonorgistrel (0.75 mg strength) has been approved as an emergency contraceptive for manufacture and import in the country. However, since this use is a new indication, the product would fall within the definition of new drug under Rule 122-E of the Drugs and Cosmetics Rules. Permission for New Drugs should be given by office of DCG (I).

It is understood that the licence for marketing has been granted by State Drug Controller of Maharsthra. M/s Cipla Ltd., has, therefore, been directed to obtain permission from the office of the DCG (I) after depositing the required fee and other documents.